The Quest for Quality Mammography--Safety, Accuracy, and Cost Optimization

Murray A. Reicher, M.D.
Radiology Medical Group, Inc.
DR Systems, Inc
San Diego, CA

Mammography Goals

- Optimization of:
  - Accuracy
  - Safety
  - Cost

Determinants of Accuracy, Safety, and Cost

- Expertise of readers
- Adjunct technology and methods such as CAD, double reading, tech preview which may improve lesion detection
- The image acquisition technology quality, cost, and efficiency
- Required technologies for display, archive, and transport of either digital or film-screen mammograms
- The cost of mandated regulatory activities to ensure quality
- Others factors???

The Conundrum

- The factors that control accuracy, safety, cost are not always aligned
  - Examples:
    - Digital technology *may* increase quality, but also increase costs
    - Double reading increases accuracy, but also increases costs
    - Greater breast compression or radiation, could increases image quality, but could be unsafe if overapplied
    - Data compression may negatively impact image quality, but increase access to experts

A Logical Solution

- Balance-- optimization of mammography requires an understanding of the balance between quality, safety, and cost and the determinants of each factor.

Mind over Matter Theory

- While the highest technical quality is always an essential goal, we have reached a technical quality threshold where incremental improvements in technology have a far smaller effect upon safety, quality, and cost compared to the expertise of the reader.

Published Evidence

- Digital vs. Film Screen technology--marginal if any statistically proven differences in quality, safety, and cost
- CAD, Double reading: 5-20% increase in cancer detection rate, with increased cost and often more false positives
- Expert readers: 150-200% increase in cancer detection rates, with lower costs and less false positives

Impacts of Expert Readers

- Sickles et al: Radiology 2002;224:861-869
  - Cancer detection rates for screening
    - Experts: 6/1000 Generalists: 3.4/1000
  - Recall rates for screening
    - Experts: 4.9% Generalists: 7.1%
  - Cancer detection rates for diagnostic
    - Experts: 59/1000 Generalists: 36.6/1000
  - Recall rates for diagnostic
    - Experts: 15.8% Generalists: 9.9%

Data from Private Grp#1

- 13,000 mammo's in 2003
- Among 7 radiologist who read at least 350 mammograms (range 350-6096), range of biopsy proven breat cancers per 1000 mammograms read was 2.6 to 13 (2.6, 2.7, 2.8, 2.9, 4.3, 10.5, 13)

Data from Private Group #3

- 2003--26,216 Mammograms
  - 15 readers with each over 1000 mammograms read
    - Cancers per 1000: Range of 1.5 to 13.8
- 2002--23,577 Mammograms
  - 14 reader with each over 500 mammograms read
    - Cancers per 1000: Range of 0-23

Why Don't Experts Read All Mammo's Today???

- Not clinically practical--mammography is most often provided within the scope of a general radiology practice, increasingly breast imaging involves US, biopsies, MRI and crosses subspecialty expertise
- Not financially viable--average cost of providing mammo is slighly higher than average reimbursement ($77 in So Cal)
- Therefore, to promote expert reading, mammo's must be cost-effectively transportable, and overall production costs must decrease to provide a financial incentive for providers

Promoting Reading by Experts

- Increase transportability of mammograms
  - Digitizing film-screen mammograms
    - also facilitates comparison and lowers archive costs
    - may reduce recall rates and cancer detection rates
  - Increase use of data compression to the degree that image quality is not reduced
  - Consider data requirements of digital mammography carefully, since increased data may inhibit access to experts
  - Consider soft copy regulatory requirements that promote low-cost workstations

Data Compression

- Lossy vs Lossless is not the same as visually destructive vs visually indentical
- Consider enabling users and their physicists to document that the data compression elected does not alter image quality
- Require appropriate labeling
- Lower data compression requirement for comparison or clinician viewing

Potentially Beneficial Technologies

- Data compression
- Digitizers to promote telemammography and lower archive costs, plus CAD
- Low cost soft copy reading and double reading
- Rational reimbursement (beyond the control of the FDA)

Soft Copy Reading

- Monitor-independent regulatory approach provided there is a documented Q/A procedure
  - Example: labeling of minified images, tools to rapidly enable soft copy display, documentation of optimal image quality by regular testing
- Provide a clear q/a definition to users and vendors

Conclusion

- Mind over Matter--improving mammography safety, accuracy, and cost can be best achieved by enabling and promoting adoption of technologies that increases the probability of reading by experts
- A clear and logical policy for digitizing film-screen mammo’s, data compression, and soft copy reading q/a in needed.

Questions for the FDA

- When is an image an “identical” copy?
  - Can one digitize and destroy film mammo
  - Can one use lossy, but non-destructive data compression
  - What about comparison exam? Referring doctor image distribution?
- Can one provide a CD instead of film as an “original”?
- Is there an accepted non-film based Q/A technique for MQSA?